Calithera Biosciences Reports Third Quarter 2020 Financial Results and Recent Highlights

November 5, 2020

--Calithera to Provide Corporate Update via Conference Call and Webcast at 2:00 p.m. PT on November 5, 2020--

SOUTH SAN FRANCISCO, Calif., Nov. 05, 2020 (GLOBE NEWSWIRE) -- Calithera Biosciences, Inc. (Nasdaq: CALA), a clinical-stage biotechnology company focused on discovering and developing novel, small-molecule drugs for the treatment of cancer and other life-threatening diseases, announced today its financial results for the third quarter ended September 30, 2020.

"To date, 2020 has been a significant year for Calithera as we've made remarkable progress to advance our clinical development efforts across our pipeline and work toward reporting our first pivotal trial results with our lead candidate glutaminase inhibitor telaglenastat, while continuing to strengthen our cash position," said Susan Molineaux, PhD, president and chief executive officer of Calithera. "We look forward to reporting top-line results from our pivotal CANTATA trial evaluating telaglenastat in renal cell carcinoma in late fourth quarter of 2020 or early first quarter 2021. We also announced recently the initiation of the first clinical trial to evaluate our novel arginase inhibitor in cystic fibrosis, and the initiation of our first clinical trial evaluating telaglenastat in people with non-small cell lung cancer whose tumors have KEAP1 or NRF2 genetic mutations."

Third Quarter 2020 and Other Recent Program Highlights

- **Progress continues toward top-line data readout of pivotal Phase 3 CANTATA randomized trial of telaglenastat and cabozantinib in advanced renal cell carcinoma (RCC).** The CANTATA trial is a global, randomized, double-blind clinical trial of telaglenastat combined with cabozantinib, in patients with advanced or metastatic RCC who have received one or two prior treatments. The trial enrolled 444 patients at multiple centers globally. The primary endpoint is progression-free survival (PFS). Calithera expects to report top-line efficacy and safety data from the trial in late fourth quarter of 2020 or early first quarter 2021.
- **KEAPSAKE randomized trial evaluating telaglenastat in non-small cell lung cancer (NSCLC) patients with a KEAP1 or NRF2 genetic mutation enrolled first patient in September.** Mutations in the KEAP1/NRF2 pathway, which occur in an estimated 20 percent of NSCLC patients, are associated with aggressive tumor growth and poor outcomes for patients. The double-blind KEAPSAKE trial will enroll approximately 120 patients with stage IV non-squamous NSCLC with tumors that have the KEAP1 or NRF2 mutation. Patients will be randomized to receive telaglenastat or placebo, in combination with pembrolizumab, carboplatin and pemetrexed. The study will evaluate the safety and investigator-assessed PFS of telaglenastat plus this standard-of-care chemo-immunotherapy regimen. Calithera anticipates sharing interim data from the KEAPSAKE trial in 2021.
- **ENTRATA Phase 2 study of telaglenastat with everolimus in RCC survival analysis completed.** The ENTRATA trial was a randomized, double-blind, trial designed to evaluate the safety and efficacy of telaglenastat in combination with everolimus versus placebo with everolimus in patients with advanced clear cell RCC who have been treated with at least two prior lines of systemic therapy, including at least one prior VEGFR-targeted tyrosine kinase inhibitor. The trial enrolled 69 patients. The primary endpoint was PFS per investigator assessment with a predetermined threshold of $p \leq 0.2$ one-sided. Top-line results were reported in June 2019. Telaglenastat, when added to everolimus, doubled the median PFS in heavily pretreated patients with advanced RCC to 3.8 months as compared to 1.9 months for everolimus alone, and reduced the risk of disease progression or death by 36% (HR=0.64, p=0.079 one-sided). Although the study was not powered for survival, it was evaluated as a secondary endpoint, and is now mature enough to be reported. Based on the data cutoff of September 30, 2020, the median overall survival is 14.4 months vs. 9.7 months in the telaglenastat and control arms, respectively (HR=0.80, p=0.24 one-sided).
- **Pfizer clinical collaboration investigating the CDK4/6 inhibitor IBRANCE® with telaglenastat expanded to evaluate the combination in pancreatic cancer patients.** In July 2019, Calithera initiated a Phase 1/2 trial of the combination of telaglenastat plus Ibrance in patients with solid tumors including expansion cohorts in KRAS-mutated colorectal cancer and KRAS-mutated non-small cell lung cancer. In November, Calithera announced the expansion of this collaboration to include an additional cohort of patients with pancreatic ductal adenocarcinoma (PDAC) whose tumors harbor mutations in both KRAS and CDKN2A.
- **CB-280 arginase inhibitor program advanced**. In October, Calithera presented a trial in progress poster at the North American Cystic Fibrosis 2020 Virtual Conference. The presentation included preclinical study results which suggest CB-280 significantly improved lung function and reduced Pseudomonas aeruginosa colony-forming units in pre-clinical models. Arginase inhibition with CB-280 resulted in improved central airway resistance in CFTR knockout mice, and decreased lung infection in wild type and DeltaF508-CFTR-expressing mice infected with Pseudomonas aeruginosa. Enrollment in the Ph1b study is ongoing and Calithera expects to share interim data in 2021. In November, Calithera was awarded up to $2.4M from the Cystic Fibrosis Foundation to support clinical development of CB-280.

- **INCB001158 program continued progress.** INCB001158, an internally discovered molecule, is being evaluated in multiple clinical trials for the treatment of patients with solid tumors both as a monotherapy, in combination with anti-PD-1 immunotherapy, and in multiple chemotherapy regimens. While Calithera remains committed to and confident in the INCB001158 development program, Calithera decided to opt out of co-development obligations with Incyte in order to focus resources on internal development programs.
- **Preclinical data presented from CB-668 IL4I1 program**. CB-668 is an investigational first-in-class, potent, orally administered IL4I1 inhibitor as a novel immuno-oncology approach to cancer. New preclinical data for CB-668 will be presented at the Society for Immunotherapy of Cancer (SITC) Virtual Meeting November 11-14, 2020.

Selected Third Quarter 2020 Financial Results

Cash, cash equivalents and investments totaled $137.7 million at September 30, 2020.

Research and development expenses were $18.2 million for the three months ended September 30, 2020, compared to $17.2 million for the same period in the prior year. The increase of $1.0 million was due to a $1.9 million increase in the telaglenastat program and a $1.5 million increase in the CB-280 program, partially offset by a $1.0 million decrease in the INCB001158 program and a decrease of $1.4 million in early stage research.

General and administrative expenses were $4.7 million for the three months ended September 30, 2020, compared with $3.9 million for the same period in the prior year. The increase of $0.8 million was primarily related to an increase in higher personnel-related and facility costs.

Interest and other income, net was $0.2 million for the three months ended September 30, 2020, compared to $0.8 million for the same period in the prior year, mainly as a result of lower interest rates.

Net loss for the three months ended September 30, 2020 was $22.7 million, or $0.32 per share.

Conference Call Information

Calithera will host an update conference call today, Thursday, November 5, at 5:00 p.m. Eastern Time/2:00 p.m. Pacific Time. The call may be accessed by dialing (855) 783-2599 (domestic) or (631) 485-4877 and referring to conference ID 6869011. To access the live audio webcast or the subsequent archived recording, visit the Investors section of the Calithera website at https://ir.calithera.com/investor-overview. The webcast will be recorded and available for replay on Calithera's website for 30 days.

About Calithera

Calithera Biosciences is a clinical-stage biopharmaceutical company pioneering the discovery and development of targeted therapies that disrupt cellular metabolic pathways to preferentially block tumor cells and enhance immune-cell activity. Driven by a commitment to rigorous science and a passion for improving the lives of people impacted by cancer and other life-threatening diseases, Calithera is advancing a pipeline of first-in-clinic, oral therapeutics to meaningfully expand treatment options available to patients. Calithera is headquartered in South San Francisco, California. For more information about Calithera, please visit www.calithera.com.

Forward Looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "may," "will," "expect," "anticipate," "estimate," "intend," "poised" and similar expressions (as well as other words or expressions referencing future events, conditions, or circumstances) are intended to identify forward-looking statements. These statements include those related to Calithera's clinical trials, the clinical and commercial potential of its product candidates; the receipt of top-line efficacy and safety data in the CANTATA trial; the timing of enrollment of the randomized trial in NSCLC patients with genetic mutation NRF2/KEAP1 and the presentation of interim data from this trial; the safety and anti-tumor activity of telaglenastat and cabozantinib, telaglenastat in combination with everolimus, and telaglenastat plus Ibrance; the development of INCB001158 by Calithera and Incyte; and the timing that CB-280 will enter clinical trials. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. The potential product candidates that Calithera develops may not progress through clinical development or receive required regulatory approvals within expected timelines or at all. In addition, clinical trials may not confirm any safety, potency or other product characteristics described or assumed in this press release. Such product candidates may not be beneficial to patients or successfully commercialized. The failure to meet expectations with respect to any of the foregoing matters may have a negative effect on Calithera's stock price. Additional information concerning these and other risk factors affecting Calithera's business can be found in Calithera's periodic filings with the Securities and Exchange Commission at www.sec.gov. These forward-looking statements are not guarantees of future performance and speak only as of the date hereof, and, except as required by law, Calithera disclaims any obligation to update these forward-looking statements to reflect future events or circumstances.

SOURCE: Calithera Biosciences, Inc.

Calithera Biosciences, Inc.
Selected Consolidated Statements of Operations Financial Data
(in thousands, except per share amounts)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	$ 18,157	$ 17,221	$ 53,938	$ 58,388
General and administrative	4,744	3,906	14,786	12,054

Total operating expenses	22,901	21,127	68,724	70,442
Loss from operations	(22,901)	(21,127)	(68,724)	(70,442)
Interest and other income, net	167	834	1,153	2,310
Net loss	$ (22,734)	$ (20,293)	$ (67,571)	$ (68,132)
Net loss per share, basic and diluted	$ (0.32)	$ (0.38)	$ (0.99)	$ (1.52)
Weighted-average common shares used to compute net loss per share, basic and diluted	70,559	53,775	68,219	44,703

Calithera Biosciences, Inc.
Selected Consolidated Balance Sheet Financial Data
(in thousands)
(unaudited)

	September 30, 2020	December 31, 2019
Balance Sheet Data:		
Cash, cash equivalents and investments	$ 137,749	$ 157,361
Working capital	120,235	140,172
Total assets	147,708	168,768
Total liabilities	25,112	26,342
Accumulated deficit	(353,672)	(286,101)
Total stockholders' equity	122,596	142,426

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